Submitted herewith is an Information Disclosure Statement under 37 C.F.R. § 1.97(c). Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form. The listed documents were cited in the International Search Report dated March 23, 1999 from the Australian Patent Office.

In the Office Action, the Examiner objected to claims 6-14 because of improper multiple dependency. *See* Office Action, page 2. By this Amendment, Applicant has amended the claims so that no multiple dependent claim depends from another multiple dependent claim.

In the Office Action, the Examiner rejected claims 15 and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite. *See* Office Action, page 2. By this Amendment canceling claims 15 and 16, the rejection under 35 U.S.C. § 112, second paragraph, became moot.

In the Office Action, the Examiner rejected claims 1-3 and 5 under 35 U.S.C. § 102(e) as being anticipated by Anderson et al. (U.S. Patent No. 5,988,169) and rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Anderson et al.

Applicant respectfully traverses the rejection of claims 1-3 and 5 under 35 U.S.C. § 102(e) because Anderson et al. fails to disclose all of the elements recited in the claims. In order to properly anticipate Applicant's claimed invention under 35 U.S.C. § 102(e), each and every element of the claim in issue must be found, either expressly described or under principles of inherency, in a single prior art reference. Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *See* M.P.E.P. § 2131 (8th Ed., Aug. 2001), quoting *Richardson v. Suzuki Motor*

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1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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Co., 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Finally, "[t]he elements must be arranged as required by the claim." M.P.E.P. § 2131 (8th ed. 2001), p. 2100-69.

Anderson et al. fails to anticipate claim 1. For example, Anderson et al. fails to disclose a substance delivery device including, among others, "a support frame having at least two resilient arms . . . wherein each resilient arm is capable of receiving and releasing a substance delivery means," as recited in claim 1. Anderson et al. discloses a vaginal insert 36 having a main body 38. *See* col. 4, lines 24-25. "A first member or portion 48 is operably connected to . . . the main body 38" and "has a projecting end 50 . . . that is in fluid communication with a first balloon 54." Col. 4, lines 28-32. "The first balloon 54 is operably connected to the projecting end 50 and is formed from a porous membrane 56." Col. 4, lines 32-33. Anderson et al. further discloses that "[a] second projecting member or portion 58 is substantially similar to the first member 48" and "a second balloon 62 is formed from a porous membrane 64 and is operably connected to the projecting end 60." Col. 4, lines 34-35 and 39-41.

Anderson et al., however, fails to disclose that the first and second projecting members 48 and 58 are "resilient." Anderson et al. discloses that "[f]irst and second projecting members 48 and 58 are positioned so that they form a gap or opening 65 therebetween" and "[i]n use, the vaginal insert 36 is placed within the vagina 26 and oriented . . . so that the bladder neck 24 is positioned within the gap 65." Col. 4, lines 43-45 and col. 5, lines 4-7. Accordingly, rather than being "resilient," the first and second projecting members 48 and 58 of Anderson et al. are inflexible.

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1300 I Street, NW
Washington, DC 20005
202.408.4000
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Furthermore, Anderson et al. also fails to disclose that the first and second projecting members 48 and 58 are "capable of receiving and releasing" the first and second balloons 54 and 62. Alternative to the vaginal insert 36 shown in Fig. 3 and having the first and second balloons 54 and 62 formed from porous membranes 62 and 64, Anderson et al. discloses other embodiments of a vaginal insert where "the first and second balloons 54 and 62 can be replaced with hollow spheres (not shown) that define a plurality of delivery ports" or "solid spheres (not shown) that . . . are covered with a material (not shown) that can be impregnated with and release the agent." Col. 5, lines 31-33 and lines 37-41. However, Anderson et al. fails to disclose that the first and second projecting members 48 and 58 are "capable of receiving and releasing" the first and second balloons 54 and 62 shown in Fig. 3 or any other balloons.

For at least these reasons, Anderson et al. fails to anticipate claim 1.

Applicant also respectfully traverses the rejection of claim 4 under 35 U.S.C. §103(a) because the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), each of three requirements must be met. First, the references, taken alone or combined, must teach or suggest each and every element recited in the claims. *See* M.P.E.P. § 2143.03 (8th ed. 2001). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Third, a reasonable expectation of success must exist. Moreover, each of these requirements must "be found in the prior art, and not be based on applicant's disclosure." M.P.E.P. § 2143 (8th ed. 2001).

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1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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As explained above regarding claim 1, Anderson et al fails to disclose or suggest, among others, "at least two resilient arms . . . wherein each resilient arm is capable of receiving and releasing a substance delivery means. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness regarding claim 4, which depends from claim 1.

For at least the foregoing reasons, Applicant respectfully submits that claim 1 as well as claims 2-14 depending therefrom are in condition for allowance.

Finally, Applicant respectfully traverses the Examiner's Official Notice that it is well known "to release drugs into body . . . via osmosis" and would have been obvious to "select the use of osmosis in the Anderson device." Office Action, pages 3-4. , Applicant, however, respectfully submits that the Examiner's Official Notice is irrelevant because it is directed to claim 4 depending from allowable claim 1. Should the Examiner dispute the patentability of claim 1, Applicant respectfully requests that the Examiner cite a reference or references supporting the Examiner's position that it is well known "to release drugs into body . . . via osmosis" and would have been obvious to "select the use of osmosis in the Anderson device."

In view of the foregoing remarks, Applicant respectfully requests the reconsideration of this application and the timely allowance of the pending claims.

Attached hereto is a marked-up version of the changes made to the claims by this Amendment. The attachment is captioned "**APPENDIX TO AMENDMENT OF OCTOBER 17, 2002.**" Deletions appear as normal text surrounded by [ ] and additions appear as underlined text.

FINNEGAN
HENDERSON
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1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: October 17, 2002

By: _____
Chi H. Kang
Reg. No. 50,623

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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APPENDIX TO AMENDMENT OF OCTOBER 17, 2002

Amendments to the Claims:

1. (Amended) A substance delivery device for insertion into a body cavity, said device includes a support frame having at least two resilient arms which retain said device in the body cavity, wherein each resilient arm is capable of receiving and releasing a substance delivery means capable of releasing substance into the [said] body cavity.

2. (Amended) A substance delivery device as claimed in claim 1, wherein the [said] substance is a drug.

3. (Amended) A substance delivery device as claimed in either claim 1 or claim 2, wherein [the] said device is an intra-vaginal release device.

4. (Amended) A substance delivery device as claimed in claim 3, wherein the substance is released from the substance delivery means through osmosis.

5. (Amended) A substance delivery device as claimed in [any one of] claim[s] 1 [to 4], wherein the substance delivery means are rounded.

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Fax 202.408.4400
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6. (Amended) A substance delivery device as claimed in [any one of] claim[s] 1 [to 5], wherein at least one of the substance delivery means is flexibly attached to [the] a corresponding arm.

7. (Amended) A substance delivery device as claimed in claim 6, wherein the at least one of the substance delivery means is attached to the corresponding arm by a ball and socket mechanism.

8. (Amended) A substance delivery means for attachment to a substance delivery device as claimed in [any one of] claim[s] 1[-7].

9. (Amended) A substance delivery device as claimed in [any one of] claim[s] 1 [to 7], wherein the support frame is in the form of a wish bone.

10. (Amended) A substance delivery device as claimed in claim 9, wherein the arms are biased outward from a central section of the support frame.

11. (Amended) A substance delivery device as claimed in either claim 9 or claim[s] 10 characterised in that the support frame is made of nylon.

12. (Amended) A substance delivery device as claimed in any one of claims 9 to [11] 10 characterised in that that the arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed.

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13. (Amended) A substance delivery device as claimed in any one of claims 9 to [12] 10, wherein the arms are capable of interlocking for removal or insertion.

14. (Amended) A substance delivery device as claimed in any one of claims 9 to [13] 10 characterised in that the support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

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Washington, DC 20005
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Fax 202.408.4400
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